



PATENT  
Customer No. 22, 852  
Attorney Docket No. 08888.0517

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Francis BLANCHE *et al.*

Application No.: 09/970,663

Filed: October 5, 2001

For: COMPOSITION FOR THE  
PRESERVATION OF  
INFECTIOUS RECOMBINANT  
ADENOVIRUSES

Group Art Unit: 1635

Examiner: Brian Whiteman

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**DECLARATION UNDER 37 C.F.R. § 1.131**

We, Francis Blanche and Shian-Jiun Shih, state that we are the named applicants of the above-identified application and that we are co-inventors of the subject matter described and claimed therein. Prior to November 16, 1998, we, the co-inventors, had completed in France the invention as described and claimed in the above-identified application as evidenced by the following:

1. Exhibit A: Laboratory Notebook Pages 51-55 and 176 (A1-A6) of Francis Blanche, showing, a composition comprising adenoviral particles and a glycerol buffer solution at pH 8.4, wherein the buffer solution does not contain added divalent metal cations or alkali metal cations. See pages 52-53 (A2-A3), formulation #2, for example, comprises Tris/HCl and 10% glycerol at pH 8.4 (hereinafter referred to as "formulation #2"). The addition of adjuvants, such as sucrose or Tween20 is shown, for example, at page 176, formulations C and D. Formulation #2 is shown to be

useful for preserving adenoviruses. See page 55 (A5), stable viral titer after 15 days of storage in formulation #2. Some compositions were tested for stability after  $-20^{\circ}\text{C}$  or  $4^{\circ}\text{C}$  storage, indicating that the  $-20^{\circ}\text{C}$  frozen viral compositions were thawed to test viability. See page 176 (A6), last three lines from the bottom.

2. The present specification at page 17, first formulation in the Table, shows a formulation identical to formulation #2 of Exhibit A;
3. Example 3 of the present specification, at pages 18-19, shows that a formulation identical to formulation #2 of Exhibit A has a stable viral titer after 15 days of storage, similar to the 15-day storage stability of formulation #2 shown on page 55 (A5) of Exhibit A.

While the dates have been redacted, the undersigned testify that all experiments described herein were conducted before November 16, 1998.

We declare further that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further, that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patents issuing thereon.

Dated: \_\_\_\_\_, 2003

By: \_\_\_\_\_  
Francis Blanche

Dated: Aug 18, 2003

By: Shian-Jiun Shih  
Shian-Jiun Shih